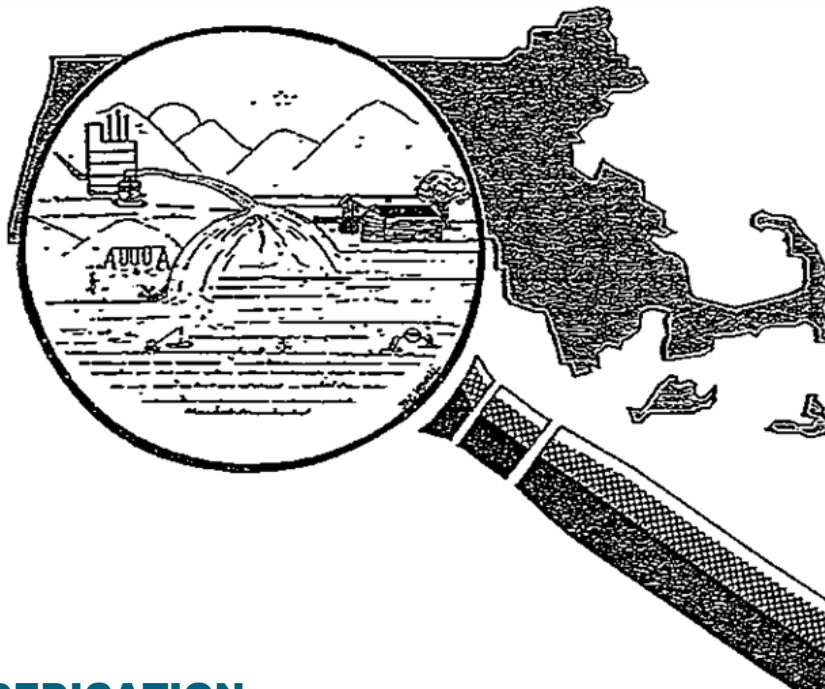


ENVIRONMENTAL HEALTH ASSESSMENT PROTOCOL

PROTOCOL FOR COMMUNITY-SPECIFIC ENVIRONMENTAL HEALTH ASSESSMENTS



DEDICATION

This protocol is dedicated to Doctor John Cutler who pioneered environmental epidemiology in the state of Massachusetts.

Dr. Cutler was a career medical officer with the rank of captain in the U.S. Public Health Service. Prior to coming to the Massachusetts Department of Public Health (MDPH), Dr. Cutler was a research fellow at the National Institute of Health in Washington from 1959-1961. Dr. Cutler was also medical director with the World Health Organization in Geneva where he conducted epidemiological studies in Yugoslavia, Ghana, Tunisia, Senegal and New Zealand.

Dr. Cutler instilled good public health practice in all of the MDPH projects in which he was involved. Those who were fortunate enough to work with him miss him greatly.

***"OUR WORK IS FOR
THE FAR FUTURE
AS WELL AS FOR
THE PRESENT, AND
AT THIS VERY
OPENING OF OUR
LABORS WE
SHOULD TRY TO
PLACE OURSELVES
ABOVE THE
REGION OF MERELY
LOCAL OR
TEMPORARY
EXCITEMENT OR
PARTISAN
WARFARE, IN
ORDER THAT WE
MAY ACT WISELY
AND FOR THE
ULTIMATE GOOD
OF THE WHOLE
PEOPLE."***

Dr. Henry I. Bowditch
First Chair of the Massachusetts
Board of Health

Prepared By:

Bureau of Environmental Health
Massachusetts Department of
Public Health



November 1992

Revised August 1998

Revised October 2012

Revised September 2015

The Bureau of Environmental Health (BEH) has a broad mission of protecting the public health from a variety of environmental exposures. The BEH responds to environmental health concerns and provides communities with epidemiologic and toxicological health assessments. In addition to investigating potential environmental exposure concerns and perceived disease elevations, the Bureau is also responsible for ensuring compliance with regulations related to community sanitation, radiation control, food safety, and the prevention of childhood lead poisoning. The Bureau uses a team/systems approach in solving environmental health problems by calling upon the expertise that exists across its various programs. Staff include epidemiologists, toxicologists, physicians, geographic information system (GIS) specialists, risk communicators, environmental scientists, engineers, health educators, regulators, and a variety of public health researchers. The Bureau is comprised of nine programs:

- Childhood Lead Poisoning Prevention Program
- Community Assessment Program
- Community Sanitation Program
- Environmental Epidemiology Program
- Environmental Health Clinical Outreach and Education Program
- Environmental Toxicology Program
- Food Protection Program
- Indoor Air Quality Program
- Radiation Control Program

An organizational chart of the BEH is presented in Figure 1.

Public awareness and concern over the potential health effects resulting from environmental exposures continue to increase. There are currently 31 National Priority List (NPL) or Superfund sites, two proposed NPL sites, and 343 additional sites designated by the United States Environmental Protection Agency (USEPA) under investigation in Massachusetts. Further, as of 2012, the Massachusetts Department of Environmental Protection (MassDEP) reports that more than 4,300 confirmed or suspected hazardous waste sites are being assessed or cleaned up in the state. Concerns over these and other areas suspected to be environmentally contaminated result in numerous requests to the BEH for toxicological and epidemiologic community health assessments. These requests are made by individual residents, citizen groups, state legislators, local boards of health, the media, and other state agencies.

In addition, a cooperative agreement with the federal Agency for Toxic Substances and Disease Registry (ATSDR) has allowed the BEH to work with staff from the ATSDR to comply with the federal timelines for Public Health Assessments at National Priority List sites as mandated by the Superfund Amendment and Reauthorization Act (SARA). This work has been carried out largely in the Community Assessment and Environmental Toxicology Programs.

CHILDHOOD LEAD POISONING AND PREVENTION PROGRAM (CLPPP)

The CLPPP was established in 1972 for the prevention, screening, diagnosis, and treatment of lead poisoning, including the elimination of sources of poisoning. The program mandate requires universal blood lead screening for children ages 0-3 years and age four for high risk communities.

COMMUNITY ASSESSMENT PROGRAM

The Community Assessment Program (CAP) was established in 1987 to provide a coordinated government response for residents with environmental health concerns. The program was established in response to the recommendations made in the *Report of the Study Commission on Environmental Health, 1984*. The CAP's goals are to educate the public on the relationship of exposure opportunities to environmental contaminants and potential human health risks; keep an open line of communication between the BEH and concerned residents; and perform efficient preliminary analyses of environmental health concerns. The CAP serves a triage function for the decision-making process in the Bureau (Figure 2). Much of the preliminary environmental health assessment work in the BEH is either performed by or in collaboration with CAP staff.

COMMUNITY SANITATION PROGRAM

The Community Sanitation Program's primary mission is the prevention of avoidable death, injury, and disability through the regulation and enforcement of standards for housing, recreational camps for children, swimming pools, family-type campgrounds, farm labor camps, and correctional facilities (as stipulated in the State Sanitary Code). Staff in the program provide education and consult with local boards of health and other state agencies.

ENVIRONMENTAL TOXICOLOGY PROGRAM

The Environmental Toxicology Program provides residents, communities, and other state and federal agencies with toxicological assessments of environmental data provided by the MassDEP and the US Environmental Protection Agency. Using environmental and biomonitoring data, program staff conduct exposure-based health assessments. Staff also provide support related to pesticide and fish toxics issues as well as evaluations related to beach monitoring and drinking water quality surveillance.

ENVIRONMENTAL EPIDEMIOLOGY PROGRAM

The Environmental Epidemiology Program designs and conducts follow-up studies and research in response to problems identified by the Community Assessment, Environmental Toxicology, and Indoor Air Quality Programs. Staff conduct analytical epidemiological studies that typically involve development of a study protocol, approval by a human subjects review board, administration of questionnaires, data analysis, and peer review.

ENVIRONMENTAL HEALTH CLINICAL OUTREACH AND EDUCATION PROGRAM

The Environmental Health Clinical Outreach and Education Program provides information, education, and outreach to health professionals and the general public on the effects of environmental hazards. The program works closely with the other BEH programs.

FOOD PROTECTION PROGRAM

The Food Protection Program's (FPP) mission is to ensure the wholesomeness, safety, and security of food and other consumer products in Massachusetts. The FPP accomplishes its objectives by conducting inspections, collecting samples, conducting special investigations, responding to consumer complaints and food borne illness reports, and conducting vulnerability assessments of food manufacturers and distributors.

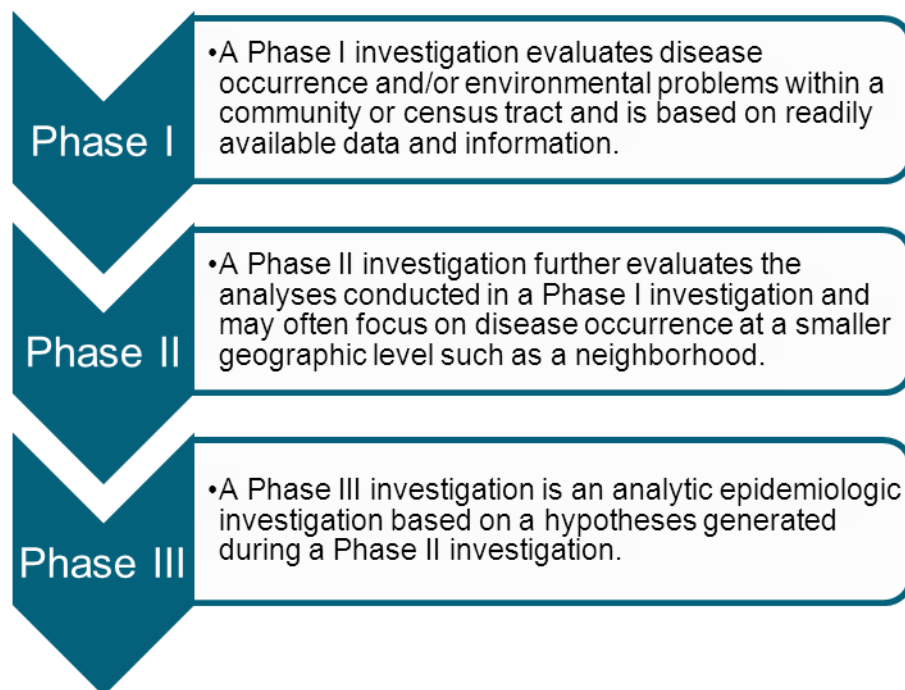
INDOOR AIR QUALITY PROGRAM

The Indoor Air Quality Program conducts indoor air quality studies in public buildings and schools in Massachusetts. It also provides technical assistance in chemical emergency responses and maintains the Massachusetts Substance List.

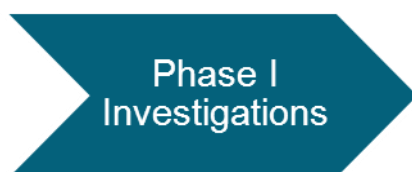
RADIATION CONTROL PROGRAM

The Radiation Control Program enforces regulations pertaining to all sources of ionizing radiation in Massachusetts through a system of licensing, registration, and inspection. The program also regulates some forms of non-ionizing radiation and licenses radiologic technicians who apply radiation to people in medical settings.

The BEH environmental health assessment investigative process consists of a three-phase program:



Schematic diagrams of the BEH investigative approach are presented in Figures 3, 4, and 5.




Phase I investigations generally rely on readily available information. Requests (most often telephone inquiries) for information and/or assistance regarding environmentally related health concerns are directed to the appropriate BEH staff member.

Calls triaged to the Community Assessment Program are recorded on a CAP telephone inquiry report within a computerized tracking database (Figure 6). The telephone inquiry report records the staff person taking the call, the person calling, the city or town the caller is from, the nature of the request, the action taken, and any special circumstances that may exist. The tracking database cross references phone calls by community, subject, and the staff person taking the call. This helps to eliminate duplication of effort and allows for quick retrieval of critical information for a variety of purposes.

When a phone call or letter is received about a suspected elevation in disease occurrence (most often cancer incidence), many times it is a matter of providing public education. The concern can be addressed either verbally over the telephone or written in a short letter. For example, CAP staff typically discuss with callers information on the prevalence of cancer and the etiologies and risk factors associated with particular cancer types. Each member of the CAP staff is equipped with a listing of primary cancer types and their known or suspected risk factors. Staff also have access to aggregate cancer incidence data for individual Massachusetts communities and census tracts via a desktop tool referred to as the SIR Calculator.

In general, CAP staff review the appropriate health outcome data that are readily available for the community or census tract of concern. This information is then provided to the concerned individual along with information regarding the risk factors that may influence the incidence of a particular disease. If this information is sufficient to address the concern and nothing appears unusual when compared to the statewide experience and/or the epidemiological literature, then the request is considered to be completed. However, when the initial review of health outcome data indicates that a significant elevation or the potential for an environmental exposure may exist or may have existed in the past, the individual is instructed to submit a written request to the Bureau Director for a Phase II investigation to further evaluate the data.

In 2008, BEH launched its Environmental Public Health Tracking (EPHT) website, making health and environmental data readily available to the public. The website was developed and is maintained through a cooperative agreement with the federal Centers for Disease Control and Prevention (CDC) as part of a national effort to make health and environmental data more available to the public and policymakers. CAP staff routinely refer callers to the website (www.mass.gov/dph/matracking) for information and data on environmental hazards (such as air pollutants), exposure to environmental hazards (such as childhood blood lead levels), and health effects potentially related to exposures (such as asthma and cancer). If users of the EPHT website have any questions, contact information is given so that an EPHT staff person can provide assistance: email: MA-EPHT@state.ma.us; 1-800-319-3042.



Phase II Investigations

A Phase II investigation is an investigation of descriptive health outcome data that involves more detailed analyses and often includes a qualitative evaluation of disease occurrence at a smaller geographic level than a census tract (i.e., neighborhood). In addition to compiling information on the number of diagnoses of a particular disease in an area compared to the number that would be expected based on the statewide experience, a Phase II investigation also reviews

available information on pertinent risk factors. A Phase II investigation can include an evaluation of existing environmental data (i.e., no new data are collected) and information on the plausibility of an association with environmental exposures.

Upon receipt of the written Phase II request, a CAP staff member sends written acknowledgement of receipt informing the individual of the type of assessment that will be conducted and the anticipated timeline for completion. Often, the city/town board of health (and when appropriate, the state or local legislative offices and any advocacy groups that may exist within the community) is informed in writing that the CAP is initiating an investigation. A community advisory committee may also be established depending upon the scope and depth of the investigation.

When conducting a Phase II investigation, the appropriate data source is first identified from within the MDPH (for example, hospital discharge data or cancer incidence data). Occasionally, sources of health information located outside the MDPH are used, such as patient medical records when patient consent is obtained. Existing environmental data are collected from the MassDEP, the USEPA, and from other city/town sources when available. CAP staff often work in conjunction with staff from the Environmental Toxicology Program in the analysis of environmental data.

Health outcome data are evaluated using standard descriptive epidemiology methods involving the calculation of prevalence estimates, standardized incidence or mortality ratios, and 95% confidence intervals. Factors that may influence disease occurrence such as race, sex, socioeconomic status, smoking, and occupation are also evaluated. In addition, the geographic distribution of cases is analyzed to determine whether any unusual clustering of cases may exist. The results of these analyses are evaluated in relation to the existing environmental data. A report describing the findings of the Phase II investigation is written and typically contains the following:

Background	Methods	Results	Discussion	Conclusions and Recommendations
<ul style="list-style-type: none">•Includes a statement of the concern, how and why the investigation was initiated and other historical information that may be of significance	<ul style="list-style-type: none">•Includes an explanation of and rationale for data collection and data analysis	<ul style="list-style-type: none">•Includes a narrative and graphic/tabular presentation of the findings	<ul style="list-style-type: none">•Includes additional explanation of the methods and findings in the context of what is known about the disease and possible associations with environmental exposures as well as data and methodological limitations	<ul style="list-style-type: none">•States the major findings and, when appropriate, describes the type and scope of recommended follow-up activities

The completed CAP Phase II report is subject to rigorous internal review. Draft reports are reviewed by the BEH and CAP Directors, the BEH Deputy Director, and other program directors when appropriate. Other MDPH staff may be asked to review a draft report as well depending on the report focus and the staff expertise. When the review process is complete and the reviewers' comments have been incorporated, a final report is issued.

Recommendations of a Phase II investigation may consist of: 1) a public health action (such as an intervention program); 2) collection of initial or additional environmental monitoring data; 3) additional activities such as collecting residential or occupational histories, conducting interviews, or reviewing medical records or; 4) a Phase III follow-up investigation.

When a Phase III investigation is recommended, the type and scope of the investigation is planned in conjunction with staff from the Environmental Epidemiology Program who design and conduct the follow-up investigation. Environmental Toxicology staff are also frequently involved in this decision-making process.




Public Release

Release of a CAP Phase II report is handled in different ways depending upon who initiated the request, the needs of the community, and/or the findings and recommendations of the report.

Most often, the release of a CAP report involves contacting the individual(s) who initiated the request and the city/town health department to inform them that the report is forthcoming. The report is accompanied by a letter, which is drafted to highlight the findings and encourage contact with the CAP if there are any questions or comments. Copies of the report are subsequently posted on the BEH's website. [It should be noted that no personally identifying information is made available in the report or on the website.]

Other times, when a request is initiated by a large community group or recommendations have been made for a follow-up investigation, CAP staff will arrange for a public meeting to release the results of the report. The meeting is usually scheduled during the evening at a local public building to assure access for all those interested within the community. At the public meeting, attendees are provided with a fact sheet and copies of the full report are made available to those who request them. CAP staff present the background, methods, results, and conclusions of the investigation and address any questions from the audience. To ensure that all questions are answered, the phone number of the CAP is provided to individuals attending the meeting. Prior to the public release of the report, local and state officials are briefed on the findings and the public health implications.



Phase III Investigations

A Phase III investigation is an analytical epidemiological field study. These investigations are usually conducted by the Environmental Epidemiology Program, but may be conducted by CAP staff in collaboration with Environmental Epidemiology Program staff, depending upon the availability

of resources and the depth of the investigation. Staff from the Environmental Toxicology Program are often involved in these investigations, usually in an advisory capacity. A Phase III investigation is intended to further evaluate the findings of the CAP Phase II investigation. It also may be undertaken to confirm exposure so that appropriate interventions can be implemented. A Phase III investigation may involve case interviews, a case-control study, and/or collection of new environmental data.

The decision criteria for initiating a Phase III study are usually qualitative. They include the following: an environmental exposure appears possible or the occurrence of an adverse health outcome is significantly greater than would be expected *and* the relationship between environmental factors and health outcomes appears biologically plausible. It is possible that all of these pieces of information may not exist at the start of a Phase III investigation. In such situations, the decision to conduct a Phase III study may be to use more sophisticated methods of case ascertainment, exposure assessment, and determination of environmental exposure potential. Some examples of situations that support the decision to move forward with a Phase III investigation are:

- Significant human exposure is believed to be occurring or has occurred in the past, however, the pathway may or may not be defined.
- The population potentially exposed can be identified.
- Reports of excess disease occurrence warrant reasonable concern or public health action.
- Biologic plausibility exists between the potential exposure and the reported disease occurrence.
- Additional criteria related to availability of biologic markers and adequate sample size may be appropriate.

All Phase III investigations establish a community advisory committee, which usually consists of a small number of residents, the board of health, and local city/town officials. This committee acts as a liaison between the community involved in the investigation and the staff in the Environmental Epidemiology Program and serves to represent the concerns and interests of the community regarding the investigation being conducted. Staff from the Environmental Epidemiology Program meet as needed with the community advisory committee to provide updated information on the status of the investigation. Often the community advisory committee serves as a valuable resource in regard to data collection and retrieval of important information about the community. The community advisory committee also provides input on the study design or type of investigation that will be conducted.

Once the design or type of investigation is determined, the Environmental Epidemiology Program prepares a scientific protocol for the investigation. This protocol details the exact methodology and study design that will be employed. The protocol is then reviewed by experts from various agencies and institutions throughout the United States. The community advisory committee also reviews the scientific protocol prior to the initiation of the investigation.

Phase III investigations are often collaborative efforts with federal agencies. They may include studies contracted under MGL c. 21E, the state law that pertains to the investigation, assessment, and clean-up of hazardous waste sites in Massachusetts. MGL c.21E is also known as the state Superfund law. Section four of MGL c. 21E allows for funds to be expended to better evaluate the health status of residents potentially exposed to state Superfund sites.

When criteria for doing a Phase III investigation are met, external funding sources must be identified. This is largely due to the need for fiscal and staffing resources beyond that which exist within the BEH or the MDPH. Depending upon the scope, study design, and identification of a funding source, conducting the investigation may take several years.

Once a Phase III report has been completed, it undergoes external peer review. The nature of the investigation will dictate the appropriate members to be selected to conduct the peer review.

Recommendations of a Phase III report may be in the form of:

- Public health actions □ these may include issuing drinking water advisories, recommendations for restricting public access, and undertaking other primary, secondary, and tertiary prevention activities.
- Environmental remediation □ the MDPH has no authority to require or implement remedial activities. However, BEH may make recommendations to the MassDEP and USEPA to reduce and/or eliminate environmental exposures through remediation.
- Lowering of a health standard □ a recommendation can be made to reduce an existing standard to a lower level more protective of public health.
- Additional study □ at the completion of a Phase III investigation focused on testing a specific hypothesis, a follow-up study may be recommended which is generally discussed with academic institutions.

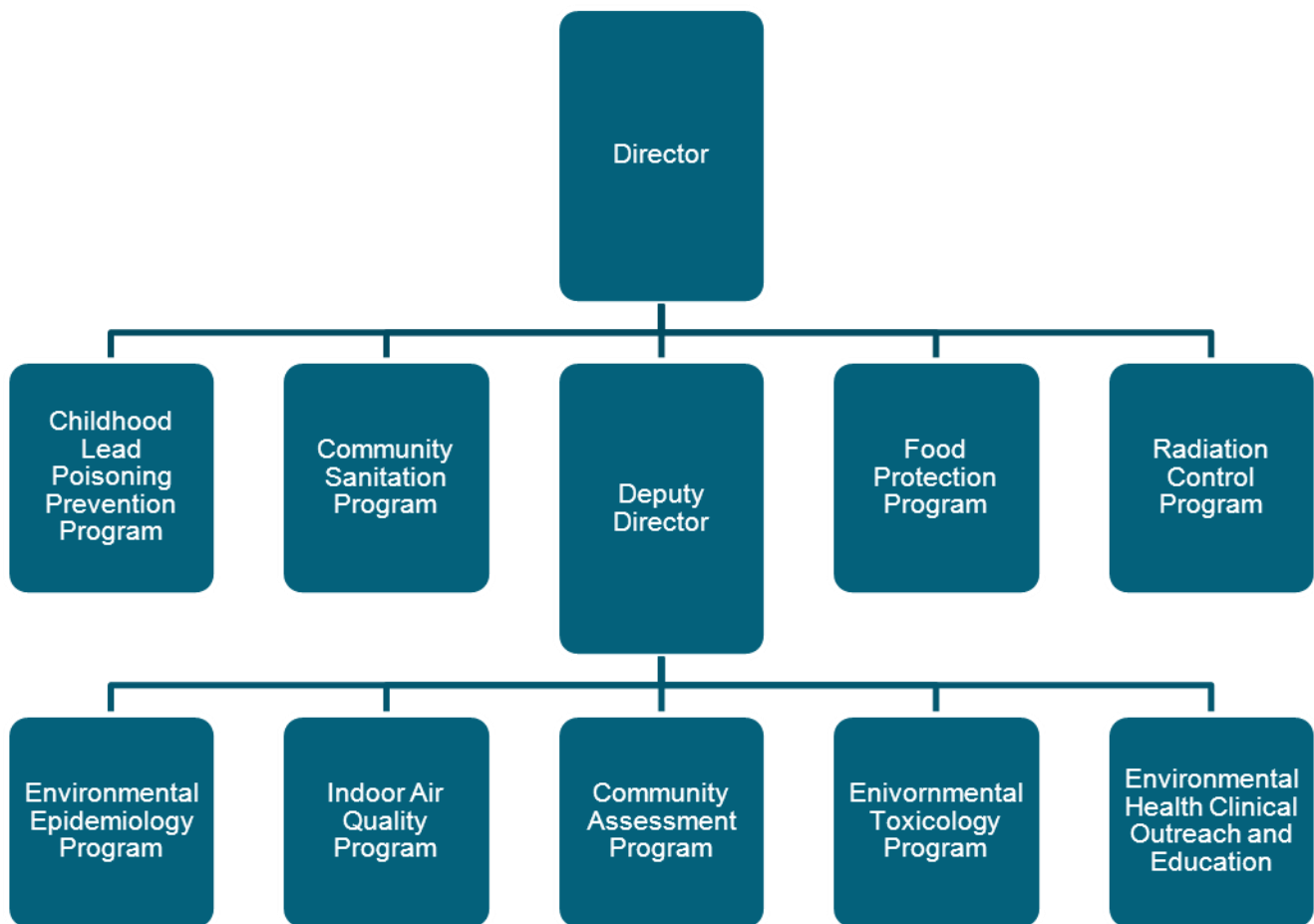
Communities that have been involved in Phase III investigations are carefully monitored on an annual basis for disease outcomes of concern and/or environmental exposure potential. If continuing trends are detected, MDPH officials initiate a decision-making process to determine the appropriate action.

For more information regarding the BEH, or other environmental and health agencies, please call or write:

The Bureau of Environmental Health
Massachusetts Department of Public Health
250 Washington Street, 7th Floor
Boston, Massachusetts 02108-4619
617-624-5757
617-624-5777 (fax)

This information is provided by the Bureau of Environmental Health within the Department of Public Health

FIGURE 1: BUREAU OF ENVIRONMENTAL HEALTH



**FIGURE 2: BUREAU OF ENVIRONMENTAL HEALTH
TRIAGE SYSTEM**

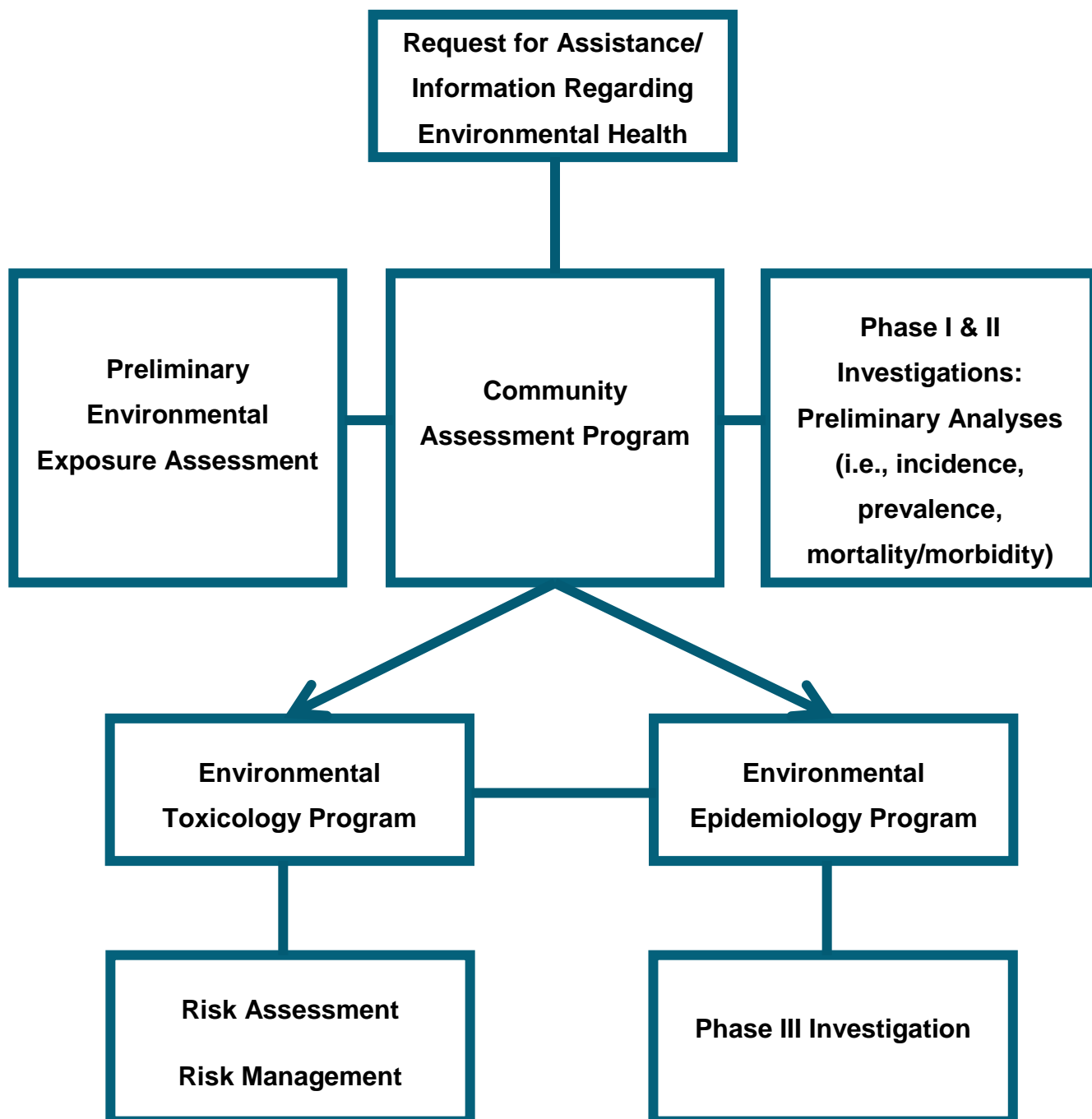


FIGURE 3: DIAGRAM OF BEH PHASE I INVESTIGATION

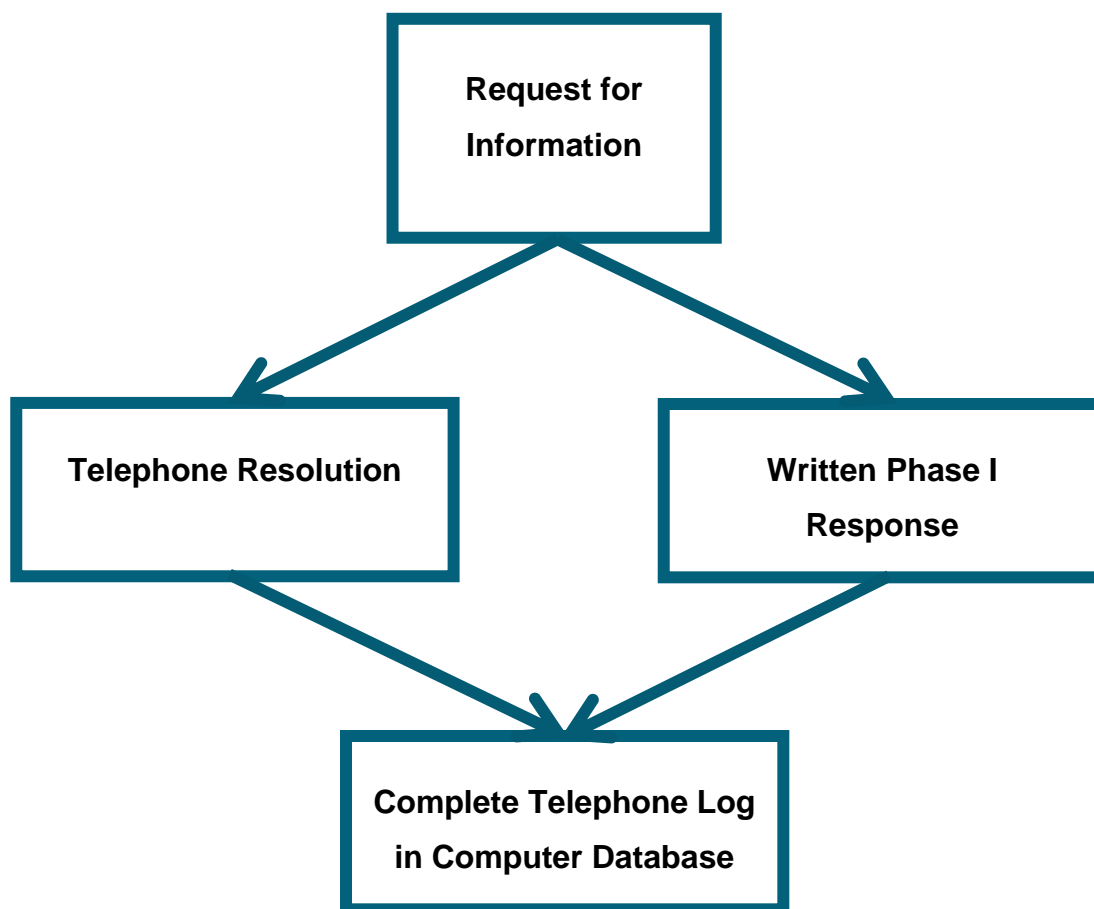


FIGURE 4: FLOW DIAGRAM OF BEH PHASE II INVESTIGATION

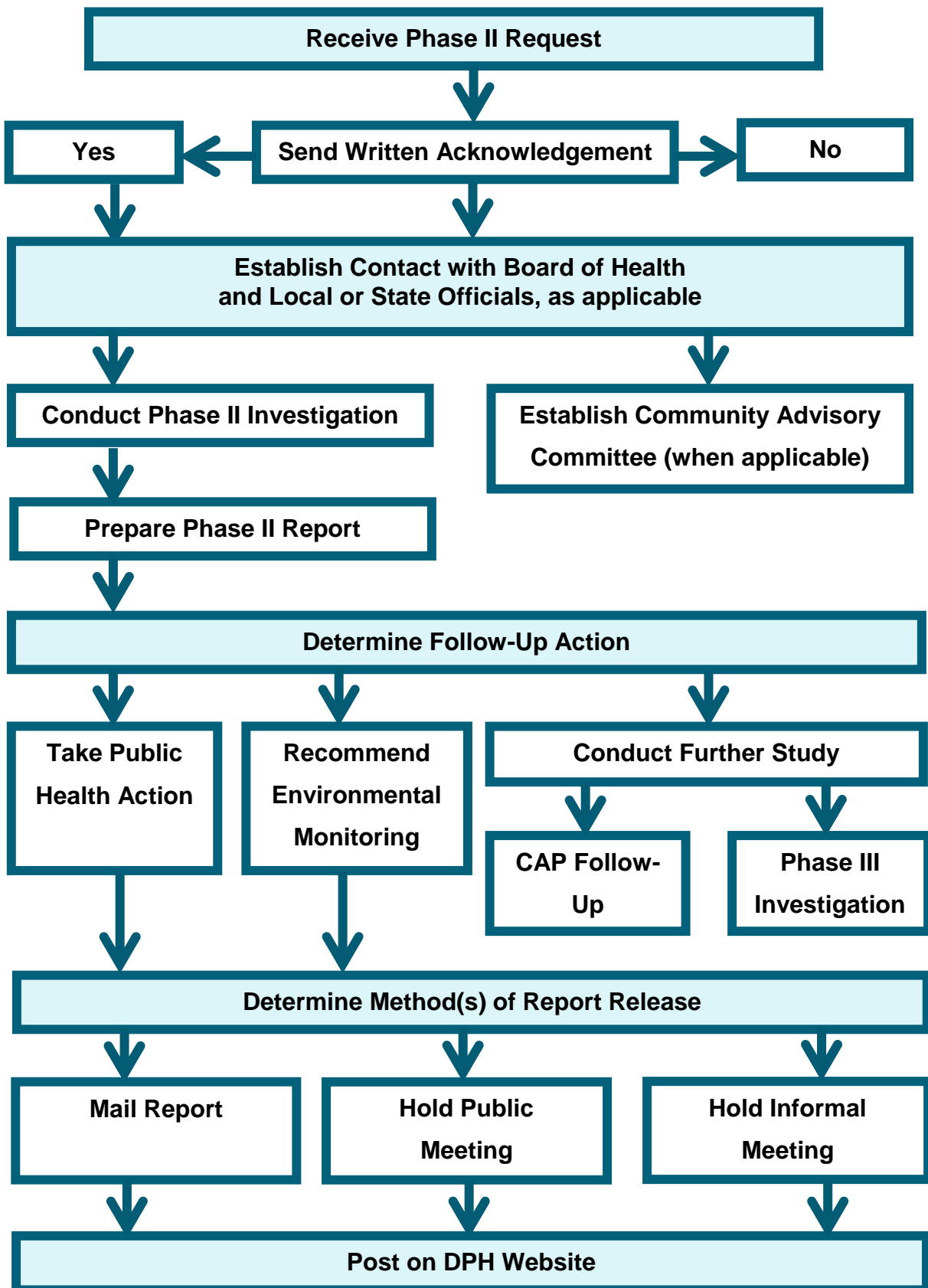


FIGURE 5: FLOW DIAGRAM OF BEH PHASE III INVESTIGATION

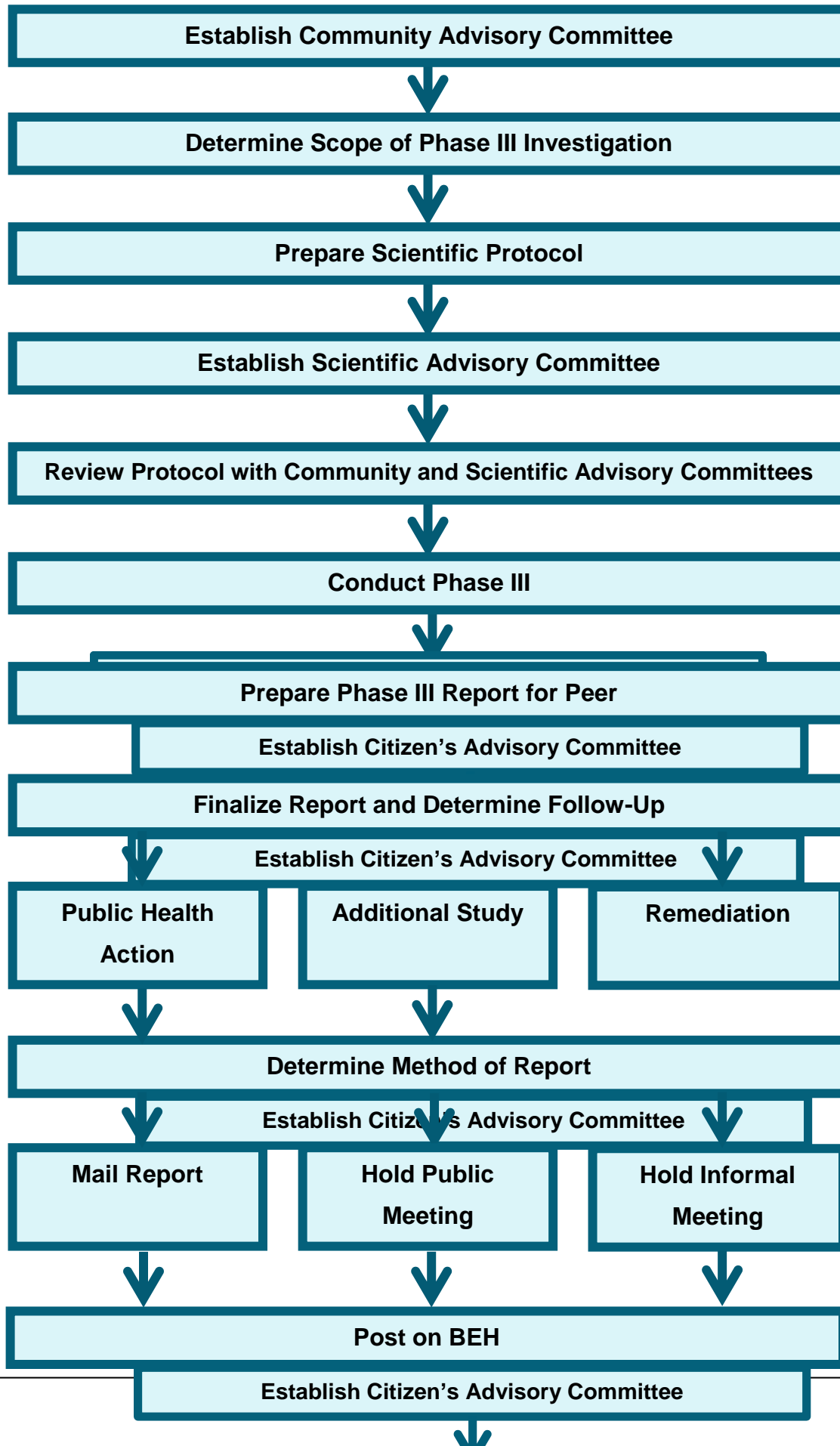


FIGURE 6: CAP ELECTRONIC PHONE LOG

Center for Environmental Health Electronic Telephone Tracking System			
Tracking Information		Caller's Information	
Tracking #	AutoN	Title	First Name Last Name
Time of Call	2:21 PM	Address	
Date of Call	10/11/2012	City	State MA Zip Code
Staff Member		Home Phone #	Email
Contact Method	Telephone	Cell Phone #	Agency/Affiliation
Program Name		Fax #	
Type of Call		Work Phone #	Extension
Classification of Caller's Concern			
City/Town of Concern	County of Concern		
		Health	Environment
Request			
Action /			
Record: 1 of 1		NUM	
Identification number for the phone log			

☐ Confidential

Phone Log Contains Individually Identifiable